

**REMARKS/ARGUMENTS**

Claims 1-16 were pending in the instant application. Claim 16 has been withdrawn. The following remarks, in conjunction with the above amendment, are believed to be fully responsive to the Office Action.

**THE REJECTIONS UNDER 35 U.S.C. § 103  
SHOULD BE WITHDRAWN**

Claims 1-15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Griffiths et al., WO03/059397 ("Griffiths") in view of the combined disclosures Yngve, Int. Diss. Abs. 2001, 62 ("Yngve") and Bottcher et al., and US 5,439,863 ("Bottcher") and in further view of Maier-Borst et al., GB2056471A ("Maier-Borst"). In response, Applicants submit that each of the rejections should be withdrawn for the reasons stated below.

Per the Examiner's request on page 7 of the current Office Action that "the method of the instant claims do not provide for the amount/concentration of chelating agent required for reaction with  $^{68}\text{Ga}^{3+}$ " Applicants respectfully request why this amount/concentration needs to be expressly claimed. And Applicants respectfully disagree that such a request needs to be claimed. Unlike Maier-Borst, in the present invention, gallium-68 is eluted from a commercial generator already in ionic form. In particular our claims 1-15 consider: i) The preconcentration of gallium-68 which is needed for the efficiency of the labeling complexing reaction. Namely, the specific radioactivity for the chelator conjugated peptide labeling was

increased 200-fold. ii) The volume was decreased 30 – fold, namely, from 6 mL to 200  $\mu$ L. This makes a 30 – fold increase in peptide or any other macromolecule concentration. iii) The chelating  $^{68}\text{Ga}$ -labeling reactions are sensitive to the presence of competing metal ions therefore it is important to purify the  $^{68}\text{Ge}/^{68}\text{Ga}$  generator eluate from those elements. The ability of metal ions to form complexes with hydrochloric acid differs. The adsorbability of the negatively charged complexes of metals differs as well.

Further, unlike the prior art, the present invention discloses a concentration of  $^{68}\text{Ga}^{3+}$ , which is in the picomolar to nanomolar to micromolar range after the elution in an anion exchanger. Hence, it is possible to reduce the amount of chelating agent in a subsequent complex formation reaction, which considerably increases the specific radioactivity. This result is important for the production of  $^{68}\text{Ga}$ -radiolabelled PET tracers that comprise a bifunctional chelating agent; i.e. a chelating agent linked to a targeting vector, as the increase in specific radioactivity enables the reduction in amount of such tracers when used in a patient.

It is therefore respectfully submitted that the 35 U.S.C. 103(a) rejections of claims 1-15 as being unpatentable over Griffiths in view of the combined disclosures Yngve and Botcher and in further view of Maier-Borst be withdrawn.

#### **DOUBLE PATENTING**

Claims 1, 3-7 and 15 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 8-14 of co-pending Application No. 10/552,206. In

response, Applicants submit that claims will be amended or cancelled if the instant application is indicated to be allowable.

Further, claims 1, 3-7, and 15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-14 of copending Application No. 10/552,206. Additionally, claims 1-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 8-15, 18, and 19 of copending Application No. 10/552,206. Further, claims 1-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 8-13 of copending Application No. 11/358,681. In response, Applicants submit that terminal disclaimers will be filed once the instant application is indicated to allowable.

**CONCLUSION**

In view of the remarks herein, Applicants believe that each ground for rejection or objection made in the instant application has been successfully overcome or obviated, and that all the pending claims are in condition for allowance. Withdrawal of the Examiner's rejections and objections, and allowance of the current application are respectfully requested.

The Examiner is invited to telephone the undersigned in order to resolve any issues that might arise and to promote the efficient examination of the current application.

Respectfully submitted,

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